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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,757	04/16/2004	Jeffrey M. Linnen	GP146-04.UT	8545

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EXAMINER
SALMON, KATHERINE D

ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
04/18/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/825,757	LINNEN ET AL.	
	Examiner	Art Unit	
	KATHERINE SALMON	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *116,124-131,139-144,153,160,161,170-177,182 and 183* is/are pending in the application.

4a) Of the above claim(s) *131,139-144,153,160,161,170-174,182 and 183* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *116,124-130 and 175-177* is/are rejected.

7)☐ Claim(s) *124-125, 176-177* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/06/2008 has been entered.

2. Claims 116, 124-131, 139-144, 153, 160-161, 170-177, 182-183 are pending. Claims 1-115, 117-123, 132-138, 145-152, 154-159, 162-169, and 178-181 are cancelled. Claims 131, 139-144, 153, 160-161, 170-174, and 182-183 are withdrawn as being drawn to a nonelected invention.

3. Claims 131, 139-144, 153, 160-161, 170-174, and 182-183 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/26/2006.

4. This action contains rejections for Claims 116, 124-130, 175-177. Response to arguments follows.

Priority

5. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). The disclosure of the prior-filed applications, Application No. 60/469294, 60/465428, 60/464049, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The applications fail to disclose SEQ ID No. 3, 24, or 25, therefore there does not appear to be support for the applicant's presently claimed invention in these provisional applications. As a result the earliest filing date of record is deemed to be 4/16/2004.

Response to Arguments

The reply did not traverse the denial of priority to the prior-filed applications, Application No. 60/469294, 60/465428, 60/464049. Therefore the filing date of record is being maintained as 4/16/2004.

Withdrawn Objections and Rejections

6. The objection to Claims 178-181 made in section 6 of the previous office action is moot based on the cancellation of the claims.

7. The rejection of the claims under 35 USC 112/second paragraph made in section 7 of the previous office action is moot based upon the amendments to the claims and cancellation of claims.

Claim Objections

8. Claims 124-125 and 176-177 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. With regard to Claims 124-125 both describe the base sequence as a sequence selected from the group consisting of SEQ ID No. 3, its complement, and the DNA equivalents thereof. Claim 124 describes a target binding portion consisting of a base sequence selected from the group consisting of SEQ ID No. 3, or its complement, and the DNA equivalents thereof. Claim 125 describes a base sequence of a probe wherein the base

sequence consists of a base sequence selected from the group consisting of SEQ ID No. 3, its complement, and the DNA equivalents. Therefore because of the consisting language of Claim 124 the two claims encompass the same limitations. This seems to be the same base sequence as described in Claim 116.

With regard to Claims 176-177 both describe the base sequence a base sequence selected from the group consisting of SEQ ID No. 3, its complement, and the DNA equivalents thereof Claim 176 describes a target binding portion consisting of a base sequence selected from the group consisting of SEQ ID No. 3, or its complement, and the DNA equivalents thereof. Claim 177 describes a base sequence of a probe wherein the base sequence consists of a base sequence selected from the group consisting of SEQ ID No. 3, its complement, and the DNA equivalents. Therefore because of the consisting language of Claim 176 the two claims encompass the same limitations. This seems to be the same base sequence as described in Claim 175.

Claim Rejections - 35 USC § 112/New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 175-177 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Upon review of the specification, the specification does not appear to provide support for the recitation of “at least 18 contiguous bases of a base sequence selected from the group consisting of SEQ ID NO:24, the DNA equivalent thereof”. The amendments to the claims raise issues of new matter because the amendments include length limitations of the base sequence which is not supported in the instant specification. Claim 175 require the new amendments of a base sequence of which "includes at least 18 contiguous bases of a base sequence selected from the group consisting of SEQ ID No: 24" and the new limitation of a sequence which "includes at least 18 contiguous bases of a base sequence selected from the group consisting of SEQ ID No. 25". These limitations consist of new matter because the instant specification does not provide support for the amendments. While the specification discloses probes in general, there is no disclosure of the phrase “at least 18 contiguous bases of a base sequence selected from the group consisting of SEQ ID NO: 24, the DNA equivalent thereof”.

The reply points to claims 169 as support for the amendments of Claim 175 (p. 9 4th paragraph). However, the length limitations in claim 169 are drawn to length limitations of SEQ ID No. 3 and not length limitations of nucleotides of the base sequences. Further, the reply points to the specification on p. 5 lines 3-8, and p. 19 lines 18-27 (p. 9 4th paragraph). The limitations found on p. 5 and p. 19 are drawn to length limitations of the probe length and not limitations of the number .of contiguous bases of

the base sequence.

These amendments to the claims, therefore, constitute new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. The claims are being broadly interpreted based on amendments to the claims. The claims have been amended to “a base sequence selected from the group consisting of SEQ ID No. 3, its complement, and the DNA equivalents thereof”. The claim is broad in two aspects. First, “a base sequence" can be broadly interpreted as ANY fragment of SEQ ID No. 3, its complement, or the DNA equivalent. Therefore any base sequence having one nucleotide in common with SEQ ID No. 3, its complement, or the DNA equivalent could be broadly interpreted as encompassing the claimed base sequence. Second the phrase “the DNA equivalents thereof” can be interpreted broadly to include any RNA which would detect SARS-CoV. Therefore based on these broad interpretations of the claims, the following 35 USC 102(e) rejection is being set forth.

11. Claims 116, 124-130, and 175-177 are rejected under 35 U.S.C. 102(e) as being anticipated by Peiris et al. (US Patent Application Publication 2005/0009009 A1 January 13, 2005).

Peiris et al. teaches the use of oligonucleotides for a diagnostic assay for detecting SARS.

With regard to Claims 116, 124, 125-126, 175-177, Peiris et al. teaches a methodology to produce oligonucleotides to detect the SARS virus. Peiris et al. teaches primers for use in amplifying the mRNA or genomic RNA of the SARS virus is based on known synthesizing methods (p. 7 paragraph 58). Peiris et al. teaches the exact length of primer will depend on the temperature, buffer, and nucleotide composition (p. 7 paragraph 58). Peiris et al. teaches the primer must prime the synthesis of extension products in the presence of the inducing agent for amplification (p. 7 paragraph 58).

Peiris et al. teaches primers and probes for polynucleotides of the SARS virus can be developed using known methods (p. 7 paragraph 59). Peiris et al. teaches primers are preferred to be as close as possible to the probe without overlapping the probe (p. 7 paragraph 59). Peiris et al. teaches the G-C content of the primers should be in the 20% to 80% range (p. 7 paragraph 59). Peiris et al. teaches it is preferred to avoid runs of an identical nucleotides especially guanine (p. 7 paragraph 59). Peiris et al. teaches the preferred melting temperature of each primer is 58 to 60 (p. 7 paragraph 59). Peiris et al. teaches the five nucleotides at the 3' end of each primer is preferred to not have more than two G or C bases (p. 7 paragraph 59). Peiris et al. teaches probes can be designed using software such as Primer Express (p. 7 paragraph 60). Peiris et

al. teaches it is preferable to keep the G-C content in the 20%-80% range and to avoid runs of an identical nucleotide (p. 7 paragraph 60)/

Peiris et al. teaches the size of the primers used to amplify a portion of the mRNA is at least 10, 15, 20, 25, or 30 nucleotides in length (p. 7 paragraph 62).

Peiris et al. teaches that besides the SARS virus there are two known serogroups of human cornoviruses (229E and OC43) (p. 27 paragraph 251). Peiris et al. teaches the primer sets used in the present assay do not have homology to either of the strains so therefore they do not cross-react with the strains (p. 27 paragraph 251). Therefore these primer sets include "a base sequence" or "DNA equivalents" of SEQ ID NO. 3, 24, and 25. Further, Peiris et al. teaches the sequence analyses of the available sequences in regions of the OC43 polymerase gene indicate the SARS virus is genetically distinct from OC43 (p. 27 paragraph 251).

With regard to Claims 127-129, Peiris et al. teaches using nucleotides in a RT-PCR to detect SAS virus (Abstract). Peiris et al. teaches making primers and probes based on the genomic sequence of hSARS virus to use in TaqMan assays (Abstract). With regard to Claims 127-129, Peiris et al. teaches the probe is a Taqman probe, which consists of an oligonucleotide with a 5'reporter (luminescent) dye and a 3' quencher dye (a pair of interacting labels consisting of a luminescent and a quencher in which the probe is detectably labeled) (p. 6 paragraph 54).

With regard to Claim 130, Peiris et al. teaches using hybridization conditions which are stringent conditions and include a temperature ranging from 50°C to 65°C (this range includes 60°C) (p. 3 paragraph 26).

With regard to Claim 175, Peiris et al. teaches oligonucleotide-based kits comprising a detectably labeled oligonucleotide, which hybridizes to the sequence of the SARS virus and a pair of primers to amplify the nucleic acid molecule (p. 8 paragraph 65).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. The following 35 USC 103(a) rejection is a reiteration of a rejection made of record in the final rejection mailed 11/06/2007. Response to Arguments follows. It is noted that this 35 USC 103(a) encompasses a narrower interpretation of the claimed invention than the 35 USC 102(e) rejection presented above.

14. Claims 116, 124-130, 175-177 are rejected under 35 U.S.C. 103(a) as being unpatentable over GenBank Accession Number NC_004718.1 (NCBI GenBank Accession Number April 14, 2003) in view of Peiris et al. (US Patent Application Publication 2005/0009009 A1 January 13, 2005).

GenBank Accession Number NC_004718 (April 14, 2003) discloses the complete genomic sequence of the SARS coronavirus. With regard to Claims 116, 124-125, and 175-177, NC_004718 discloses a sequence in which SEQ ID No. 3, 24, and 25 are contained within. SEQ ID No. 3 is identical to nucleotides 18162-18206. SEQ ID No. 24 is identical to nucleotides 18243-18273. SEQ ID No. 25 is identical to nucleotides 18162-18206. Therefore, NC_004718 discloses a sequence, which comprises the SEQ IDs in the claimed invention.

NC_004718, however, does not teach the specific fragments of SEQ ID Nos. 3, 24, 25 for detection of the SARS virus, labels, or a kit.

Peiris et al. teaches the use of oligonucleotides for a diagnostic assay for detecting SARS.

With regard to Claims 116, 124-125, and 175-177, Peiris et al. teaches a methodology to produce oligonucleotides to detect the SARS virus. Peiris et al. teaches primers for use in amplifying the mRNA or genomic RNA of the SARS virus is based on known synthesizing methods (p. 7 paragraph 58). Peiris et al. teaches the exact length of primer will depend on the temperature, buffer, and nucleotide composition (p. 7 paragraph 58). Peiris et al. teaches the primer must prime the synthesis of extension products in the presence of the inducing agent for amplification (p. 7 paragraph 58).

Peiris et al. teaches primers and probes for polynucleotides of the SARS virus can be developed using known methods (p. 7 paragraph 59). Peiris et al. teaches primers are preferred to be as close as possible to the probe without overlapping the probe (p. 7 paragraph 59). Peiris et al. teaches the G-C content of the primers should be in the 20% to 80% range (p. 7 paragraph 59). Peiris et al. teaches it is preferred to avoid runs of an identical nucleotides especially guanine (p. 7 paragraph 59). Peiris et al. teaches the preferred melting temperature of each primer is 58 to 60 (p. 7 paragraph 59). . Peiris et al. teaches the five nucleotides at the 3' end of each primer is preferred to not have more than two G or C bases (p. 7 paragraph 59). Peiris et al. teaches probes can be designed using software such as Primer Express (p. 7 paragraph 60). Peiris et al. teaches it is preferable to keep the G-C content in the 20%-80% range and to avoid runs of an identical nucleotide (p. 7 paragraph 60)/

Peiris et al. teaches the size of the primers used to amplify a portion of the mRNA is at least 10, 15, 20, 25, or 30 nucleotides in length (p. 7 paragraph 62).

Peiris et al. teaches that besides the SARS virus there are two known serogroups of human cornoviruses (229E and OC43) (p. 27 paragraph 251). Peiris et al. teaches the primer sets used in the present assay do not have homology to either of the strains so therefore they do not cross-react with the strains (p. 27 paragraph 251). Further, Peiris et al. teaches the sequence analyses of the available sequences in regions of the OC43 polymerase gene indicate the SARS virus is genetically distinct from OC43 (p. 27 paragraph 251).

Peiris et al. teaches using nucleotides in a RT-PCR to detect SAS virus (Abstract). Peiris et al. teaches making primers and probes based on the genomic sequence of hSARS virus to use in TaqMan assays (Abstract).

With regard to Claims 127-129, Peiris et al. teaches the probe is a Taqman probe, which consists of an oligonucleotide with a 5'reporter (luminescent) dye and a 3' quencher dye (a pair of interacting labels consisting of a luminescent and a quencher in which the probe is detectably labeled) (p. 6 paragraph 54).

With regard to Claim 130, Peiris et al. teaches using hybridization conditions which are stringent conditions and include a temperature ranging from 50°C to 65°C (this range includes 60°C) (p. 3 paragraph 26).

With regard to Claim 175-177, Peiris et al. teaches oligonucleotide-based kits comprising a detectably labeled oligonucleotide, which hybridizes to the sequence of the SARS virus and a pair of primers to amplify the nucleic acid molecule (p. 8 paragraph 65).

Therefore, the ordinary artisan would have been motivated to select any number of oligonucleotides including SEQ ID No. 3, 24, and 25 for amplifying and detecting the SARS virus. The art of designing probes and primers at the time the invention was made was very well described in the art. The art uses alignment programs to align sequences of interest and then uses algorithms to select and test probes and primers for their desired function of either detecting or distinguishing particular organisms. Designing primers and probes, which are equivalents to those taught in the art, is routine experimentation. The prior art is replete with guidance and information necessary to permit the ordinary artisan in the field of nucleic acid detection to design primers and probes. The claimed primers are prima facie obvious over the cited references in the absence of secondary considerations, given the extensive teachings in the art. It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to use the SARS sequence as disclosed by NC_004718 to create new oligonucleotides to detect the SARS virus using the guidance of the design constraints as taught by Peiris et al. to obtain equivalent alternative oligonucleotides of the claimed invention such as SEQ ID No. 25 and 24. The ordinary artisan would be motivated to have designed and tested new oligonucleotides from fragments of NC_004718 to obtain additional oligonucleotides that function to detect the SARS virus and identify oligonucleotides with improved properties.

Response to Arguments

The reply traverses the rejection. A summary of the arguments presented in the reply is presented below with response to arguments following.

(A) The reply asserts that the probes are limited to comprising target binding portion that consists of or is contained within and includes at least 18 contiguous bases of the base sequence of SEQ ID No. 3, its complement or a DNA equivalent (p. 10 last paragraph). The reply asserts that examples 1 and 2 of the instant application illustrate two probes having sequences which meet the limitations of the claimed probe (p. 10 last paragraph). The reply asserts that one probe is 18 contiguous bases and one is 21 contiguous bases of SEQ ID NO. 3 (p. 10 last paragraph). The reply asserts that in Example 1, SEQ ID No. 44 and 45 did not hybridize and that they encompass only the need of SEQ ID No. 3 (p. 11 1st paragraph). The reply asserts that therefore the instant application shows that various probes are unpredictable in detecting SARS-CoV.

These arguments have been fully considered but have not been found persuasive.

In the instant case it is clear that the prior art teaches the critical parameters necessary for probe selection including the preferred sequence regions and methodology to select probes which doe no cross react with similar viruses such as 229E and OC43, and a sequence which spans the region of interest (p. 27 paragraph 251). Therefore, the prior art provides the information necessary to select probes and the prior art provides a reasonable expectation of success that every probe would function in a detection assay. This is not just general guidance because the prior art

provides specific guidance regarding the selection of probes for the specific detection of the SARs virus without cross-reactivity to human cornoviruses. Therefore there is a reasonable expectation of success in designing probes without secondary considerations that the claimed probes have unexpected results.

The reply seems to be pointing to support in the specification for unexpected results with the assertion that SEQ ID No. 44 and 45 which contain only a portion of SEQ ID No. 3 did not hybridize to detect the SARs virus. However, it is noted that the claims are not limited to the probes which detected the SARs virus in example 1 and 2, but rather, to a much broader claim of any sequence of SEQ ID no. 3 or any small fragment of SEQ ID No. 3 that is at least 18 contiguous bases. It is noted that these probes could encompass probes that are regions of the end of SEQ ID No. 3 which the reply is asserting would not hybridize to detect the SARs virus.

As such, applicant has not provided evidence via secondary consideration that the probes made by the suggestion and teachings of the prior art would not be equivalent structures as the claimed probes. This should not be construed as an invitation for providing evidence. As further stated in the MPEP 716.01 regarding the timely submission of evidence:

A) Timeliness.
Evidence traversing rejections must be timely or seasonably filed to be entered and entitled to consideration. In re Rothermel, 276 F.2d 393, 125 USPQ 328 (CCPA 1960). Affidavits and declarations submitted under 37 CFR 1.132 and other evidence traversing rejections are considered timely if submitted:
(1) prior to a final rejection,
(2) before appeal in an application not having a final rejection, or
(3) after final rejection and submitted
(i) with a first reply after final rejection for the purpose of overcoming a new ground of rejection or requirement made in the final rejection, or

(ii) with a satisfactory showing under 37 CFR 1.116(b) or 37 CFR 1.195, or
(iii) under 37 CFR 1.129(a).

(B) The reply asserts that the claims have been amended to recites that the test sample is exposed to isothermal conditions during the exposing step (p. 11 2nd paragraph). The reply asserts that this is unlike thermal cycling reactions and that regions for amplifying targeted nucleic acids must be demonstrated empirically (p. 11 2nd paragraph). The reply asserts that the applicants have identified optimal regions for amplifying SARS-CoV that are not predictable including regions containing at least 18 contiguous bases of SEQ ID No. 24 and 25 (p. 11 2nd paragraph). The reply asserts that 100 copy sensitivity can be achieved with amplification oligonucleotides of the claimed invention as shown in example 1 (p. 11 2nd paragraph).

These arguments have been fully considered but have not been found persuasive.

The reply further asserts that probes in isothermic reactions must be tested individually to determine the unpredictablility of probes. The claim as amended do not recite isothermal conditions during the exposing step and therefore this limitation can not be used to overcome the 35 USC 103(a) rejection presented above.

Further, the information of what is known in the art with regard to probe design in isothermic conditions versus thermal cycling conditions is not in the cited reference and the Attorney's arguments cannot take the place of evidence on the record. As stated in the MPEP, 2106 “Arguments of Counsel”

"However, it must be emphasized that arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure. See In re Budnick, 537 F.2d at 538, 190 USPQ at 424; In re Schulze, 346 F.2d 600, 145 USPQ 716 (CCPA 1965); In re Cole, 326 F.2d 769, 140 USPQ 230 (CCPA 1964). For example, in a case where the record consisted substantially of arguments and opinions of applicant's attorney, the court indicated that factual affidavits could have provided important evidence on the issue of enablement."

Conclusion

15. No Claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Katherine Salmon/
Examiner, Art Unit 1634

/Ram R. Shukla/
Supervisory Patent Examiner, Art Unit 1634